Controlled Study on the Effectiveness of a Dutch Can Do Training (CDT) in People with Relapsing Remitting Multiple Sclerosis

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To investigate the effect of a Dutch Can Do Training (CDT) on self-efficacy in people with Relapsing Remitting Multiple Sclerosis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Demyelinating disorders
Study type	Interventional

Summary

ID

NL-OMON39648

Source
ToetsingOnline

Brief title
Controlled Dutch Can Do Training (CDT) Study

Condition

- Demyelinating disorders

Synonym
Multiple sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Nationaal MS Fonds
Source(s) of monetary or material Support: Collectebusfonds

Intervention

Keyword: autonomy, Can Do Training, multiple sclerosis, self-efficacy

Outcome measures

Primary outcome

Self-efficacy-control, as measured by the Multiple Sclerosis Self-Efficacy-18 control score.

Secondary outcome

Self-efficacy-function, MSSES-18 (function score); Problem-related autonomy, Impact on Participation and Autonomy (IPA-32) problem-related score; Limitations-related autonomy, IPA-32 limitations-score; health-related quality of life, Multiple Sclerosis Quality of Life-54 (MSQoL-54) questionnaire (mental and physical scores); anxiety and depression, Hospital Anxiety and Depression Scale-14 (HADS-14) (anxiety and depression scores); cost effectiveness and cost utility, EQ-5D-5L, costs questionnaire; neurological symptoms and handicap, Expanded Disability Status Scale (EDSS) (only 1 week before CDT).

Study description

Background summary

In people with MS (PwMS) symptoms and disabilities often negatively affect self-reliance. As a result many PwMS loose their self-efficacy and autonomy. Importantly, loss of self-efficacy and autonomy has been shown to result in a decrease in health-related quality of life. One of the consequences of these developments is that PwMS do more appeal to their partners or care givers. In the U.S.A. a program (Can Do Training, CDT) has been developed that offers PwMS a way to regain their capabilities and self-efficacy. It consists of an intensive training given by a multidisciplinary team of health care professionals.

In a 12-month pilot study we investigated the feasibility and potential effectiveness of modified Dutch version of CDT. This CDT variant consists of a 3-day training (in contrast to the 5-day program in the U.S.A.) and also includes the partners of the PwMS.The available data indicate that this CDT program is fasible, as of the 97 participants only 7 (7%) discontinued the training prematurely. However, for PwMS who had recently been diagnosed the CDT turned out to be (too) confronting due to the presence in the groups of people with advanced disease and disability. We also noticed an evident need of CDT in PwMS with no partner.

Moreover, an analysis (N=44) of the 6-month data showed statistically significant differences between participants with relatively few symptoms and limitations (Expanded Disability Status Scale [EDSS] score <4,0) vs. those with more symptoms and limitations (EDSS score >4,0), and also between participants with Relapsing Remitting MS (RRMS) vs. those with progressive MS. In the EDSS<4,0-group and the RRMS group significant improvements were seen in various outcomes, whereas in the EDSS>4,0-group and the progressive group no improvements were seen. The Multiple Sclerosis Self-Efficacy-Control (MSSE-C) score in the EDSS<4,0-group had increased by 17,3% (mean) and in the RRMS group with 24,8% (mean). In addition, in the RRMS group the mental Multiple Sclerosis Quality of Life-54 Items (MSQoL-54) score had increased by 22,3% (mean) and the physical MSQoL-54 score by 12,7% (mean).

Study objective

To investigate the effect of a Dutch Can Do Training (CDT) on self-efficacy in people with Relapsing Remitting Multiple Sclerosis.

Study design

In the periode from April to December 2013 5 CDTs will be given in weekends, one CDT per weekend. Per CDT a control group will be formed that receives no CDT. Both groups complete questionnaires at the same time points. The time points are: one week before CDT, 1 month after CDT and 3 and 6 momths after CDT.
Participants will be randomized.
Primary endpoint is the Multiple Sclerosis Self-Efficacy-18 control score.

Intervention

CDT consists of training programs tailored to the personalized goals of the individual participants. The training is given by a team of experienced healh care professionals (neurologisct, MS-specialized nurse, psychiater, psychiatric nurse, physiotherapist, yga teacher). The aim of the training exercises is to explore the personal limits and thus to increase one's capabilities related to

the individual goal, which can be physical or mental.

Study burden and risks

Burden and risk.
For PwMS in the CDT group: During CDT the participants explore their limits by goal-oriented, individualized, tailored and intensive mental or physical exercices. It has been known that PwMS may experience a temporary worsening of symptoms (e.g. fatigue) after intensive physical of mental strains. These changes do not result from an increase in inflammation, completely disappear after rest, and constitute a so-called pseudo-relapse. A true relapse is only related to stress in as far it is mental, negative and chronic.
Confrontation with one's limitations and handicaps might illicit new or intense emotions. These situations are immediately recognized by the CDT team and adequately handled.
For PwMS in both groups: The strain related to the completion of the questionnaires is considered moderate as there are 4 time points in a 6-month period, the completion per time point is 70 minutes at maximum, and the questionnaires are MS-relevant.
For partners in the CDT group: During CDT the participants explore their limits by goal-oriented, individualized, tailored and intensive mental or physical exercices. To prevent this group from setting unrealistic goals, that might potentially affect their health, the partners are counseled by the team CDT members.
For partners in both groups: The burden related to the completion of thequestionnaires is minimal: 4 times in a 6-month period, with less than 20 minutes per time.
Risk for all participants: as the activities may be strenuous accidents might happen, e.g. when walking through a forets.

Benefit
PwMS may regain lost capabilities and reconquer their autonomy and improve health-related quality of life, whereas they may rebalance the relation with their partners regarding autonomy (PwMS) and care-related stress (partners).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

For people with multiple sclerosis (MS): 1) diagnosis Relapsing Remitting MS since 1 year or longer, 2) Expanded Disability Status Scale (EDSS) score less than or equal to 4.0, 3) no symptoms suggestive of a relapse, 4) no relapse in the previous 4 weeks, 5) willing and capable to participate in the investigations mentioned in the study protocol.
For partners of people with MS: willing and capable to participate in the investigations mentioned in the study protocol.

Exclusion criteria

1) Progressive type of multiple sclerosis (MS), 2) Diagnosis MS since less than 1 year, 3) Expanded Disability Status Scale (EDSS) score less higher than 4.0, 4) Symptoms suggestive of a relapse, 5) Relapse in last 4 weeks, 6) not capable to participate in the investigations mentioned in the study protocol.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-03-2013
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	11-02-2013
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	26-03-2013
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	12-06-2013
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	30-10-2013
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Not approved Date:	02-03-2015
Application type:	Amendment

Review commission:	METOPP: Medisch Ethische Toetsing Onderzoek bij Patienten en Proefpersonen (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 25770
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL42205.028.12
OMON	NL-OMON25770